4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0085]

Agency Information Collection Activities; Announcement of Office of Management and Budget

Approval; Cooperative Manufacturing Arrangements for Licensed Biologics

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Cooperative Manufacturing Arrangements for Licensed Biologics" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: On August 10, 2011, the Agency submitted a proposed collection of information entitled "Cooperative Manufacturing Arrangements for Licensed

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Biologics" to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not

conduct or sponsor, and a person is not required to respond to, a collection of information unless

it displays a currently valid OMB control number. OMB has now approved the information

collection and has assigned OMB control number 0910-0629. The approval expires on February

28, 2015. A copy of the supporting statement for this information collection is available on the

Internet at http://www.reginfo.gov/public/do/PRAMain.

Dated: March 6, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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